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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/542,144 | 07/13/2005 | Juan Ramella | P70596US0 | 9818 |

136 7590 03/27/2008

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| EXAMINER | |
|---|---|
| WIEST, PHILIP R | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3761 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 03/27/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/542,144 | RAMELLA, JUAN | |
| | Examiner | Art Unit | |
| | Phil Wiest | 3761 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2 and 4-21* is/are pending in the application.

4a) Of the above claim(s) *12-15* is/are withdrawn from consideration.

5)☒ Claim(s) *21* is/are allowed.

6)☒ Claim(s) *1,2,4,6-8,10,11 and 17-20* is/are rejected.

7)☒ Claim(s) *5,9 and 16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 April 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/7/07 has been entered.

### *Response to Amendment*

In the reply filed 12/7/08, applicant amended claims 1 and 18, and added new claim 21. Claims 1-21 are currently pending and claims 12-15 are withdrawn from consideration.

The indicated allowability of claims 6-8, 11, 19, and 20 is withdrawn in view of the newly discovered reference(s) to Laffay. Rejections based on the newly cited reference(s) follow.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 6, 7, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rochat (US 5,269,924) in view of Laffay (FR 2,766,797).

1. With respect to Claims 1 and 2 Rochat discloses a filtering apparatus 10 comprising two outer sheets and a flexible inner sheet 12 that divides the interior of the bag into a first chamber 13 and second 14 chamber (see Figure 1). The inner sheet comprises a screen that extends to the distal end (bottom end) of the bag). The two outer sheets and inner sheet are water-tightly joined at a periphery of the bag. A circular access bushing (21, 15, 16) is placed in fluid communication with the chambers such that it provides an inlet line into the first chamber and a discharge line in communication with the second chamber (see Figure 1). Rochat further discloses that the entire outer wall of the bag is watertight (Column 2, Lines 47-63). Rochat, however, does not disclose that the bushing is affixed on the side wall of the bag via a first and second aperture in the inner sheet and one of the outer sheets, nor does Rochat specifically disclose that powdered solute is disposed in the chamber, such that the bag is capable of preparing a dialysis solution.

Laffay discloses a medical bag for the preparation of dialysis solution comprising a bushing 8 built directly into the side of the bag. The bushing comprises first and second flow paths. Fluid enters the chamber through the first flow pat 22, where it is combined with powdered dialysis solution. The fluid mixes with the powder, forming dialysis fluid, and is removed from the chamber through the outlet tube 26. The outlet

tube comprises a filtration element at its entrance, such that powder does not exit the bag. The bag, therefore, functions in the same manner as claimed by applicant. It would have been obvious to one skilled in the art at the time of invention to modify the filtering apparatus of Rochat with Laffay's dual-lumen bushing and use of a filter to block the flow of powdered solute in order to create a dialysis fluid. Rochat clearly discloses the structure of the claimed device, and the use of said structure to perform the same function as taught by Laffay is does not constitute a patentable improvement over the prior art. Regarding the placement of the bushing, Laffay and Rochat both disclose bushings which are annular on the plane which projects toward the bag. The repositioning of the bushing to the side of the bag, such that an aperture would be created in the sheets provides the same functionality as the device of Rochat, and the repositioning of the bushing to the side of the bag (as taught by Laffay) would have an obvious rearrangement to one of ordinary skill in the art in view of the prior art. See MPEP § 2144.04.

With respect to Claims 6, 7, and 11, Laffay clearly suggests the placement of an annular bushing with a fluid-tight fitting on the side of the bag, said bushing having two flow paths. It would have been obvious to one of ordinary skill in the art at the time of invention to rearrange the bushing of Laffay such that the second tube is a radial tube because doing so does not provide any additional functionality over the prior art. The bushing system of Laffay is fully capable of functioning identically to the claimed bushing.

2. Claims 4, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rochat in view of Laffay, further in view of Mathieu (US 5,616,305).

3. With respect to Claim 4, Rochat and Laffay disclose the blood bag of Claim 1 (see above rejection). Rochat and Laffay, however, do not disclose that the powdered solute is sodium bicarbonate. Mathieu discloses a hemodialysis packaging unit comprising a layer of sodium bicarbonate powder 74 (Column 9, Lines 47-55). The use of sodium bicarbonite for dialysis treatment of blood is established in the art, especially when used in conjunction with powdered dialysis solution. Therefore, it would have been obvious to one skilled in the art at the time of invention to modify the system of Rochat and Laffay with the layer of sodium bicarbonate of Mathieu in order to allow for a well-established means of creating dialysis fluid for treatment of the blood. Furthermore, Laffay teaches the placement of the layer of powdered solute before the filtering layer 28 in order to prevent undisolved particles from leaving the bag. Therefore, it would have been obvious to place the sodium bicarbonate before the filter (i.e. in the first chamber) of the device of Rochat.

4. With respect to Claim 10, Rochat discloses that the inner, screen-like sheet comprised a mesh filter 12 with openings between 100 and 1000 microns that is capable of retaining an undisolved powder solute (Column 2, Lines 40-47).

5. Claims 8 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rochat in view of Laffay, and further in view of Verkaart et al. (US 2002/0030002).

Rochat discloses the bicompartment bag comprising a first and second flexible outer sheet, a flexible inner sheet 12 dividing the bag into a first and second chamber and having a perforated filter portion at the bottom of the bag. The inner and outer sheets are water-tightly sealed at the peripheries such that no leaks occur. Rochat further discloses a bushing (21, 15, 16) having a first and second flow channel therein to provide fluid communication between the first and second chambers. The bushing (21, 15, 16) comprises a plurality of cover members (17, 22) that create an air-tight seal around the bag. Rochat, however, does not disclose that the bushing is disposed on a side wall of the bag via a first and second aperture in the inner sheet and one of the outer sheets, nor does Rochat disclose a cover for sealing the entrance to the flow channels.

Laffay discloses a medical bag for the preparation of dialysis solution comprising a bushing 8 built directly into the side of the bag. The bushing comprises first and second flow paths. Fluid enters the chamber through the first flow pat 22, where it is combined with powdered dialysis solution. The fluid mixes with the powder, forming dialysis fluid, and is removed from the chamber through the outlet tube 26. The outlet tube comprises a filtration element at its entrance, such that powder does not exit the bag. The bag, therefore, functions in the same manner as claimed by applicant. It would have been obvious to one skilled in the art at the time of invention to modify the filtering apparatus of Rochat with Laffay's dual-lumen bushing and use of a filter to block the flow of powdered solute in order to create a dialysis fluid. Rochat clearly discloses the structure of the claimed device, and the use of said structure to perform the same

function as taught by Laffay is does not constitute a patentable improvement over the prior art. Regarding the placement of the bushing, Laffay and Rochat both disclose bushings which are annular on the plane which projects toward the bag. The repositioning of the bushing to the side of the bag, such that an aperture would be created in the sheets provides the same functionality as the device of Rochat, and the repositioning of the bushing to the side of the bag (as taught by Laffay) would have an obvious rearrangement to one of ordinary skill in the art in view of the prior art. See MPEP § 2144.04.

Regarding the orientation of the Bushing, Laffay clearly suggests the placement of an annular bushing on the side of the bag, said bushing having two flow paths. It would have been obvious to one of ordinary skill in the art at the time of invention to rearrange the bushing of Laffay such that the second tube is a extends radially from the central flow path because doing so does not provide any additional functionality over the prior art. Because Laffay fdisclose two separate flow tubes extending from the bushing, the bushing of Laffay is fully capable of functioning identically to the claimed bushing.

Vekaart et al. discloses a filter bag system comprising a fluid inlet and a fluid outlet. The fluid outlet comprises a removable cover portion 226 that acts as a sealing valve, said valve being openable to provide fluid communication through the channel [0022]. The removable cover 226 prevents the contamination of the fluid line by external air prior attaching a conduit, thereby reducing the risk of infection of the blood. The step of providing a sealing means to the ends of a conduit to prevent contamination is well established in the art of medical fluid containers. Therefore, it would have been

obvious to one of ordinary skill in the art at the time of invention to combine the device of Rochat in view of Laffay with the tube sealing means of Vekaart et al. in order to prevent fluids from entering the tube before it is connected to a blood source, thereby preventing infection.

## *Allowable Subject Matter*

6. Claim 21 is allowed.

Claims 5, 9, and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

The prior art teaches blood bag of Claim 1, but does not teach the layer attached to the second chamber and made from a woven or injected material, or the use of a valve comprising a thin sheet having a section having lesser strength lines that open and close the valve. Verkaart teaches the use of a valve, but none of the prior art teaches a thin sheet disposed in the second chamber that acts as a valve.

### *Response to Arguments*

7. Applicant's arguments with respect to claims 1-4, 10, and 18 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that there is no motivation to use the device of Rochat to create a dialysis fluid. This argument has not been found persuasive. The device of Rochat is

structurally similar to the claimed device, and Laffay and Mathieu clearly disclose the use of a filter to prevent undissolved solute powder from passing through the system. Given the teachings of Mathieu and Laffay, it is the examiner's opinion that one of ordinary skill in the art would have been motivated to use to filter bag of Rochat to create dialysis fluid.

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761